REMARKS

As a preliminary matter, the undersigned has submitted herewith PTO Form SB/81 (Revocation of Power of Attorney/New Power of Attorney), empowering the undersigned and his firm to take action in the present application. The required Statement under 37 CFR 3.73(b) accompanies the present paper also.

By the Action dated August 26, 2009, the Examiner provisionally rejects the presently pending claims over claims 1-33 of co-pending application Serial No. 10/072,320 (the '320 application). The rejection is framed as a provisional nonstatutory obviousness-type double patenting rejection. This rejection is improper on its face, and must be withdrawn.

The claims (now numbered 33-34, 36-57, 63-64) of the '320 application stem from a restriction requirement dated November 16, 2001, imposed by the Office on the claims of the present application. In that Action (copy appended as **Exhibit 1** for the Examiner's convenience), Examiner R.M. DeWitty took the position that claims 1-32 of the present application defined a first invention Group, and that the remaining claims of the application were drawn to distinct, though related inventions. Indeed, in the 2001 restriction requirement claims 1-32 (currently pending in the present application) and claims 33-58 (currently pending in the '320 application) were held to be not only distinct (page 2), but unrelated (page 3). For those reasons, the Office considered restriction to be proper. Following the restriction requirement, the Applicant elected claims 1-32 for examination in the present application, and filed the '320 application as a divisional application from the present application.

The Manual of Patent Examining Procedure is unequivocal. "Where restriction is required by the Office double patenting ***cannot be held*** ..." (emphasis added). *See* the MPEP §806, *at* page 800-41. The rejection is therefore improper and should be withdrawn.

All pending issues having been addressed and all rejections of record having been overcome, issuance of a prompt Notice of Allowance for the pending claims of the present application is believed to be merited and is respectfully requested. This paper is filed concurrently with an extension of time of one (1) month, tolling the response deadline to **December 26, 2009**. The Commissioner is authorized to deduct the required fee from the undersigned representative's **Deposit Account No. 11-0978.**

Respectfully submitted,

KING & SCHICKLI, PLLC



Patrick M. Torre
Registration No. 55,684

247 North Broadway
Lexington, KY 40507
(859) 252-0889

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,133	12/27/2000	Russell Mumper	50229-207	3309

7590 11/16/2001

MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER
DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
1616	5

DATE MAILED: 11/16/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Exhibit 1

Office Action Summary	Application No. 09/748,133	Applicant(s) MUMPER ET AL.	
	Examiner Robert M DeWitty	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

 I. Claims 1-32, drawn to a composition, classified in class 514, subclass 944.

 II. Claims 33-58, drawn to a composite, classified in class 424, subclass 502.

 III. Claim 59, drawn to a method of making, classified in class 426, subclass 6.

 IV. Claim 60, drawn to a method of making, classified in class 424, subclass 490.

 V. Claim 61, drawn to method of treating, classified in class 424, subclass 1.25.

 VI. Claim 62, drawn to a method of treating, classified in class 424, subclass 1.29.

2. The inventions are distinct, each from the other because:

Inventions I, II and III, IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the processes can be used to make materially different products, such as homogeneous mucoadhesive film.

Inventions I,II and V,VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product can be practiced with materially different products, such as a wax film composite.

Inventions III,IV and V,VI are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are not disclosed as capable of use together, and they have different effects (Group II being a wax-film composite).

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are not disclosed as capable of

use together, and they have different functions (Group IV forming a homogeneous mucoadhesive film).

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, and they have different operations (Group VI using a wax-film composite).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-VI, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Joseph Kim on November 7, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Michael DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
November 15, 2001



NEIL S. LEVY
PRIMARY EXAMINER